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EXAMINER
FORD, VANESSA L

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,002	Applicant(s) SCHRODER ET AL.	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAIL ACTION

1. Applicant's response filed May 22, 2002 is acknowledged. Claims 1-10 have been cancelled. Claims 11-46 have been added.

2. For clarification of the record the rejections made under 35 U.S.C. 101, pages 2-3, paragraph 1 of the previous Office action, paper No.6, the obviousness—type double patenting was made between Application No. 09,926,001 and Application No. 09,926, 002.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

4. In view of Applicant's amendment the following Objections and Rejections have been withdrawn:

a) Rejection of claims 1-10 under 35 U.S.C. 101, pages 2-3, paragraph 1, of the previous Office action.
b) Rejection of claim 1 under 35 U.S.C. 112, second paragraph, page 3, paragraph 2, of the previous Office action.
c) Rejection of claim 3 under 35 U.S.C. 112, second paragraph, pages 3-4, paragraph 3, of the previous Office action.
d) Rejection of claim 4 under 35 U.S.C. 112, second paragraph, page 4, paragraph 4, of the previous Office action.
e) Rejection of claim 5 under 35 U.S.C. 112, second paragraph, page 4, paragraph 5, of the previous Office action.
f) Rejection of claim 10 under 35 U.S.C. 103(a), pages 8-9, paragraph 8.

5. The rejection under 35 U.S.C. 103(a) as being unpatentable over Schroder et al in view of Svenson is maintained for the newly presented claims 11-15 for reasons set forth, pages 5-7, paragraph 6 of the previous Office Action.

The rejection was on the grounds Schroder teaches the use of monoglycerides as adjuvants. Schroder teaches that the parenteral or mucosal administration of a pharmaceutical formulation containing monoglycerides (i.e. mono-olein/oleic acid) improves the immune response against admixed antigens/vaccines (page 4, lines 16-25). Schroder teaches that a combination between a monoglyceride and a fatty acid can stimulate the immune system to produce antibodies and induce protective immunity (page 7, lines 6-9). Limitations such as "mucosal administration is being view as a limitation of intended use. However, it is well known in the art that lipid preparations that are used as adjuvants are not restricted to one mode of administration and can be used in many routes of administration including mucosal. Limitations such as packaging the vaccine as an aersol, spray or nose-drop package is being viewed as a limitation of design choice.
Schroder does not teach an immunizing component consisting of active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bride groups to immunogenically active carrier (IAC).

Svenson teaches the use of carbohydrate moieties (ACM) which are covalently coupled possibly via identical divalent bridge groups to immunologically active carriers (IAC). Svenson teaches that bacterial polysaccharides are classical examples of antigens are not T helper cell-dependent and mainly induce IgM class of antibodies. Svenson teaches that in immunologically immature small children, the elderly and immunosuppressed persons polysaccharides are known to be poor immunogens or not at all immunogenic. Svenson teach that polysaccharide antigens which are chemically conjugated to carriers comprising T cell epitopes are effective as vaccines. It is well known in the art that the use of adjuvants with antigens enhance the immunogenicity of the antigen.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the monoglyceride preparation as taught by Schroder to the vaccine composition comprising of consisting of active carbohydrate moieties (ACM) of Svenson because Schroder et al teach that a combination between a monoglyceride and a fatty acid can stimulate the immune system to produce antibodies and induce protective immunity (page 7, lines 6-9). It would have been expected barring evidence to the contrary, that the addition of monoglycerides to compositions consisting of carbohydrate moieties (ACM) would provide enhanced immunogenicity of antigens and the use of monoglycerides in vaccines are stable, cheaper and easy to formulate.

Applicant urges that there is no mention of the possibility of obtaining a vaccine against TB in the combined references. Applicant urges that a person skilled in the art would not expect any simple solution to obtain an improved TB vaccine composition and therefore, the inventors did not expect any positive results when TB antigens were used in combination with either the adjuvant of Schroder and/or when used as an active component in the conjugate of Svenson. Applicant urges that it would no be obvious to one of ordinary skill in the art that the adjuvant together with a conjugate vaccine comprising active carbohydrate moieties for *Mycobacterium tuberculosis* would be an effective vaccine against tuberculosis.

Applicant's arguments filed May 22, 2002 have been fully considered but they are not persuasive. The claims are directed to a vaccine formulation. Schroder teaches the use of monoglycerides as adjuvants. Schroder teaches that the administration of a pharmaceutical formulation containing monoglycerides improves the immune response against admixed antigen vaccines. Schroder does not teach an immunizing component consisting of active carbohydrate moieties (ACM) derived from M. tuberculosis which are covalently coupled, possibly via identical divalent bridge groups to immunogenically active carriers. However, Svenson teaches the use of carbohydrate moieties (ACM) which are covalently coupled possibly via identical divalent bridge groups to immunologically active carriers (IAC). It is stated that there are presently large efforts in research and development in order to obtain a safe adjuvant with high efficacy to be used in humans. Lipids are the preferred substances since they display structures that

make them biodegradables as well as the fact that they are the most important part in all biological membranes. Therefore, it would have been obvious to couple the lipid formulation of Schroder to the carbohydrate moieties which are covalently coupled via to immunologically active carriers (IAC) of Svenson. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

6. The rejection under 35 U.S.C. 103(a) as being unpatentable over Schroder et al in view of Svenson and further in view of Vercellone et al is maintained for newly presented claims 11-16, 18-27 and 29-36 for the reasons set forth in pages 7-8, paragraph 7 of the previous Office Action.

The rejection was on the grounds that Schroder and Svenson as combined *supra* do not teach lipoarabinomannan-tetanus toxoid (LAM-TT).

Vercellone et al teach lipoarabinomannan (LAM) derived from *Mycobacterium tuberculosis*. Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity. Vercellone et al teaches that stimulates double negative T cells which contributes to the protective immunity against tuberculosis. Vercellone et al teach that Lam has the ability to insert into membranes without the involvement of any receptor. Vercellone et al also teach that T lymphocytes are involved in host defense by killing infected cells (page 16). It is well known in the art that carriers such as tetanus toxoid can be chemically conjugate to antigens to improve their immunogenicity and are used as vaccines.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was to further modify the vaccine composition as combined *supra* according to the teaching of Vercellone et al because Vercellone et al teaches that lipoarabinomannan has the ability to insert into membranes without the involvement of any receptor and that lipoarabinomannan stimulates double negative T cells which contributes to the protective immunity against tuberculosis (page 16). It would have been expected barring evidence to the contrary, that the addition of lipoarabinomannan would provide enhanced immunogenicity of antigens, and therefore provide protective immunity.

Applicant urges that one of ordinary skill in the art would have no reason to combine the teaching of Schroder and/or Svenson when developing a TB vaccine as

none of these documents mention a TB vaccine. Applicant urges that there is no mention of the suitability of covalently linking LAM to a specific linker that is also bound to an immunoactivating carrier. Applicant urges that one of ordinary skill in the art would have no reason to combine the teachings of Schroder and/or Svenson when developing a TB vaccine as none of these documents mention a TB vaccine. Applicant further urges that there is no reason to combine the teaching of Schroder and/or Svenson with the teachings of Vercellone et al as Vercellone et al do not describe any specific vaccine absent the teaching in Applicant's specification.

Applicant's arguments filed May 22, 2002 have been fully considered but they are not persuasive. Applicant's arguments are not commensurate in scope with the claimed invention. Applicant appears to be arguing limitations that are not in the claims. The claims are directed to a vaccine formulation. The limitation such as "against a mycobacterium" is a limitation of intended use which carry little patentable weight to the product. The teachings of Schroder and Svenson have been described previously. Schroder and Svenson as combined do not teach lipoarabinomannan. Vercellone et al teach lipoarabinomannan (LAM) derived from *Mycobacterium tuberculosis*. Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity. Therefore, it would have been obvious to further modify the vaccine formulation of Schroder and Svenson combined according to the teaching of Vercellone et al because Vercellone et al teaches that lipoarabinomannan has the ability to insert into membranes without the involvement of any receptor and that lipoarabinomannan stimulates double negative T cells which contribute to the protective

immunity against tuberculosis (page 16). The limitation such as "mucosal administration" is being view as a limitation of intended use. However, it is well known in the art that lipid preparations that are used as adjuvants are not restricted to one mode of administration and can be used in many routes of administration including mucosal. Limitations such as packaging the vaccine as an aersol, spray or nose-drop package is being viewed as a limitation of design choice. There is nothing on the record to show that the combination of teachings would not suggest the claimed invention.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

New Ground of Rejection Necessitated by Amendment

7. Claims 11-15, 20-24 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroder *(WO 97/47320, published December 1997)* in view of *Svenson, WO 97/35613, published October 1997).*

Claims 11-15, 20-24 and 29-33 are drawn to a vaccine formulation against mycobacterium comprising as an adjuvant one or more substances.

Schroder teaches the use of monoglycerides as adjuvants. Schroder teaches that the parenteral or mucosal administration of a pharmaceutical formulation containing monoglycerides (i.e. mono-olein/oleic acid) improves the immune response against admixed antigens/vaccines (page 4, lines 16-25). Schroder teaches that a combination between a monoglyceride and a fatty acid can stimulate the immune system to produce antibodies and induce protective immunity (page 7, lines 6-9). The limitation such as "mucosal administration" is being view as a limitation of intended use. However, it is well known in the art that lipid preparations that are used as adjuvants are not restricted to one mode of administration and can be used in many routes of administration including mucosal. Limitations such as packaging the vaccine as an aersol, spray or nose-drop package is being viewed as a limitation of design choice.

Schroder does not teach immunizing component consisting of active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bride groups to immunogenically active carrier (IAC).

Svenson teaches the use of carbohydrate moieties (ACM) which are covalently coupled possibly via identical divalent bridge groups to immunologically active carriers (IAC). Svenson teaches that bacterial polysaccharides are classical examples of antigens are not T helper cell-dependent and mainly induce IgM class of antibodies. Svenson teaches that in immunologically immature small children, the elderly and immunosuppressed persons polysaccharides are known to be poor immunogens or not at all immunogenic. Svenson teach that polysaccharide antigens which are chemically

conjugated to carriers comprising T cell epitopes are effective as vaccines. It is well known in the art that the use of adjuvants with antigens enhance the immunogenicity of the antigen.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add the monoglyceride preparation as taught by Schroder to the vaccine composition comprising of consisting of active carbohydrate moieties (ACM) of Svenson because Schroder et al teach that a combination between a monoglyceride and a fatty acid can stimulate the immune system to produce antibodies and induce protective immunity (page 7, lines 6-9). It would have been expected barring evidence to the contrary, that the addition of monoglycerides to compositions consisting of carbohydrate moieties (ACM) would provide enhanced immunogenicity of antigens and the use of monoglycerides in vaccines are stable, cheaper and easy to formulate.

8. Claims 11-16, 18-27 and 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroder in view of Svenson and further in view of Vercellone et al *(Frontiers in Bioscience,1998 Aug 6;3:149-63)*

Claims 11-16, 18-27 and 29-36 are drawn to a vaccine formulation against mycobacterium, wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid and the immunizing component is lipoarabinomannan-tetanus toxoid (LAM-TT).

The teaching of Schroder and Svenson have been described previously.

Schroder and Svenson as combined *supra* do not teach lipoarabinomannan (LAM).

Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity. Vercellone et al teaches that stimulates double negative T cells which contributes to the protective immunity against tuberculosis. Vercellone et al teach that Lam has the ability to insert into membranes without the involvement of any receptor. Vercellone et al also teach that T lymphocytes are involved in host defense by killing infected cells (page 16). It is well known in the art that carriers such as tetanus toxoid can be chemically conjugate to antigens to improve their immunogenicity and are used as vaccines. The limitations such as "mucosal administration" is being view as a limitation of intended use. However, it is well known in the art that lipid preparations that are used as adjuvants are not restricted to one mode of administration and can be used in many routes of administration including mucosal.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was add the LAM of Vercellone to the vaccine as combined supra because Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity and Vercellone et al further teach that LAM stimulates double negative T cells which contributes to the protective immunity against tuberculosis. It would have been expected barring evidence to the contrary, that the addition of lipoarabinomannan would provide enhanced immunogenicity of antigens and provide for enhanced protective immunity against Tuberculosis.

9. Claims 11-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schroder, Svenson and Vercellone et al and in further view of Hansen et al *(Ann Surg, July 1976: 184(1):80-88).*

The teachings of Schroder, Svenson and Vercellone et al have been described previously.

Schroder, Svenson and Vercellone et al as combined *supra* do not teach soybean oil.

Hansen et al teach the use of soybean oil. Hansen et al teach that soybean oil emulsion can be administered with out significant vein irritation. Hansen et al further teach that soybean oil emulsion is usually well tolerated by human patients (including pediatric patients) (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was to further modify the vaccine composition as combined *supra* according to the teaching of Hansen because Hansen et al teach that soybean oil emulsion is usually well tolerated by human patients (including pediatric patients). It would have been expected barring evidence to the contrary, that the addition of soybean oil would provide nutritional enhanced for patients dependent on parenteral alimentation with fat-free solutions because soybean oil preparations are essential for fatty acid deficiencies (see the Abstract).

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al *(U.S. Patent No. 6, 350, 456, published February 26, 2000)* in view of Schroder *(WO 97/47320, published December 1997)* and in further view of Svenson, *(WO 97/35613, published October 1997).*

Claims 38-42 are drawn to a method of vaccinating a mammal against a mycobacterium having antigenically active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis*, which comprises mucosa administration to the mammal of a protective-inducing amount of a tuberculosis vaccine formulation comprising as an adjuvant.

Reed et al teach a method of vaccinating a mammal against *Mycobacterium tuberculosis* comprising administering *M. tuberculosis* antigens to guinea pigs (column 37). Reed et al teach that the immune response enhancer employed in the inventive vaccine is an adjuvant. Reed et al teach that the vaccines of the invention comprise

cytokines or chemokines and the vaccines are formulated in an oil in water emulsion (column 3).

Reed et al do not teach use of monoglycerides as adjuvants.

Schroder teaches the use of monoglycerides as adjuvants. Schroder teaches that the parenteral or mucosal administration of a pharmaceutical formulation containing monoglycerides (i.e. mono-olein/oleic acid) improves the immune response against admixed antigens/vaccines (page 4, lines 16-25). Schroder teaches that a combination between a monoglyceride and a fatty acid can stimulate the immune system to produce antibodies and induce protective immunity (page 7, lines 6-9).

Reed et al and Schroder as combined *supra* do not teach immunizing component consisting of active carbohydrate moieties (ACM) derived from *Mycobacterium tuberculosis* which are each covalently coupled, possibly via identical divalent bride groups to immunogenically active carrier (IAC).

Svenson teaches the use of carbohydrate moieties (ACM) which are covalently coupled possibly via identical divalent bridge groups to immunologically active carriers (IAC). Svenson teaches that bacterial polysaccharides are classical examples of antigens are not T helper cell-dependent and mainly induce IgM class of antibodies. Svenson teaches that in immunologically immature small children, the elderly and immunosuppressed persons polysaccharides are known to be poor immunogens or not at all immunogenic. Svenson teach that polysaccharide antigens which are chemically conjugated to carriers comprising T cell epitopes are effective as vaccines. It is well

known in the art that the use of adjuvants with antigens enhance the immunogenicity of the antigen.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was add the components of Schroder and Svenson combined to the vaccine composition used in the method of vaccinating a mammal as taught by Reed et al because Reed et al teach the immune response enhancer employed in the inventive vaccine is an adjuvant and the vaccines are preferably formulated in an oil in water emulsion (column 3). It would have been expected barring evidence to the contrary, that the addition of and adjuvant would enhancer the immunogenicity of the *Mycobacterium tuberculosis* vaccine.

11. Claims 38-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al, Schroder, Svenson and further in view of Vercellone et al *(Frontiers in Bioscience,1998 Aug 6;3:149-63)*

Claims 38-45 are drawn to a method of vaccinating a mammal against mycobacterium according to claim 38 wherein the monoglyceride preparation is mono-olein and the fatty acid is oleic acid and the immunizing component is lipoarabinomannan-tetanus toxoid (LAM-TT).

The teachings of Reed et al, Schroder and Svenson have been described previously.

Reed et al, Schroder and Svenson as combined *supra* above do not teach LAM.

Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity. Vercellone et al teaches that stimulates double negative T cells which contributes to the protective immunity against tuberculosis. Vercellone et al teach that Lam has the ability to insert into membranes without the involvement of any receptor. Vercellone et al also teach that T lymphocytes are involved in host defense by killing infected cells (page 16). It is well known in the art that carriers such as tetanus toxoid can be chemically conjugate to antigens to improve their immunogenicity and are used as vaccines. Limitations such as "mucosal administration is being view as a limitation of intended use.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was add the LAM of Vercellone to the vaccine as combined supra used in the method of vaccinating a mammal because Vercellone et al teach that LAM has a wide spectrum of immunological properties which contribute to protective immunity and Vercellone et al further teach that LAM stimulates double negative T cells which contributes to the protective immunity against tuberculosis. It would have been expected barring evidence to the contrary, that the addition of lipoarabinomannan would provide enhanced immunogenicity of antigens and provide for enhanced protective immunity against Tuberculosis.

12. Claims 38-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al, Schroder, Svenson, Vercellone et al and further in view of Hansen et al *(Ann Surg, July 1976: 184(1):80-88).*

Claims 38-46 are drawn to a method of vaccinating a mammal against mycobacterium according to claim 43, further comprising soybean oil.

The teachings of Reed et al, Schroder, Svenson and Vercellone et al have been described previously.

Reed et al, Schroder, Svenson and Vercellone as combined *supra* do not teach soybean oil.

Hansen et al teach the use of soybean oil. Hansen et al teach that soybean oil emulsion can be administered with out significant vein irritation. Hansen et al further teach that soybean oil emulsion is usually well tolerated by human patients (including pediatric patients) (see the Abstract).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was to further modify the vaccine composition as combined *supra* according to the teaching of Hansen because Hansen et al teach that soybean oil emulsion is usually well tolerated by human patients (including pediatric patients). It would have been expected barring evidence to the contrary, that the addition of soybean oil would provide nutritional enhanced for patients dependent on parenteral alimentation with fat-free solutions because soybean oil preparations are essential for fatty acid deficiencies (see the Abstract).

Status of Claims

13. No claims are allowed.

Conclusion

14. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
August 6, 2002

JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600